UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and NEW YORK STATE, ex rel. IRINA GELMAN, DPM, Plaintiffs, v. GLENN J. DONOVAN, DPM, NEW YORK CITY HEALTH and HOSPITALS CORPORATION, and PHYSICIAN AFFILIATE GROUP OF NEW YORK, P.C., Defendants.	Case No.: CV 12-5142

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Relator Irina Gelman ("Relator") fails to allege the single most important element of a claim under the False Claims Act ("FCA"): a bill submitted to a government agency containing a false claim. Without particularizing the "who, what, where, when, and why" of specific bills, it is impossible to discern from the First Amended Complaint ("Amended Complaint" or "Am. Cplt.") any misrepresentations made by any Defendant to any governmental body, let alone any that were material to Medicare or Medicaid payment, as required by the Supreme Court's recent decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). In *Escobar*, the Court held certain misrepresentations actionable because the claim forms submitted to Medicaid contained statements that amounted to false information about treatments performed and the medical professionals providing them, and because that false information plausibly may have been material to the government's payment decisions. The Court held that to plead materiality, relators must make particularized allegations tending to show that a governmental recipient of a false claim would have rejected payment had it known the truth. Relator has not adequately pleaded either the existence of a false representation in a claim submitted to the government or the materiality of any such misrepresentation.

Relator relies heavily on the so-called Teaching Physician Rule, under which a teaching provider's physical presence is required only where the provider seeks to charge Medicare for his or her own professional services in instances in which a resident is involved in the care.[1] If no bill for professional services was submitted – and none is identified – the Teaching Physician Rule is simply not implicated. Conceding this fact, Relator shifts gears and alleges that the residents were impermissibly "unsupervised." However, she has identified no context in which

[1] Under Medicaid, podiatrists' professional bills in a hospital setting are not recognized at all.

the supervision did not satisfy Medicare or Medicaid requirements, much less one for which an actual claim for reimbursement was made. These allegations amount to merely an assertion that supervision was not as *Relator* may have liked.

Relator's wishful thinking, however, cannot render false any implicit representation by Defendants that *government program requirements* were met. For example, the Medicare agency has elected not to impose *any* specific supervision requirements for inpatient hospital services because that setting necessarily affords adequate supervision of those services. Relator cannot plausibly have alleged false representations of compliance with a non-existent standard. As for *outpatient* services, the Medicare agency has required only that *some* qualified medical professional (not necessarily a podiatrist) be "immediately available to furnish assistance and direction"; absent specifically identified instances, the Court cannot plausibly infer that *no* qualified medical professional was available at a major metropolitan hospital during clinic hours when outpatient visits were performed. For Medicaid, Relator has likewise failed to allege violations of any supervision standard other than her own personal notions.

Relator also alleges that some residents at times lacked New York limited residency permits ("LRP") to receive training within a hospital GME program, but cites no bills for services in which such residents participated. Absent submission of a bill for *those services*, there can have been no misrepresentation to the Medicare or Medicaid agency as to compliance with any LRP-related regulations, even if such regulations existed and compliance therewith was material to payment. But there are no such regulations – which is no doubt why Relator seeks to equate possession of an LRP with a *license* to practice podiatry, which is not required of residents in training programs. The Medicare and Medicaid authorities that Relator cites concerning licensing do not apply to LRPs.

Finally, Relator alleges that cost reports submitted to Medicare and Medicaid were false insofar as they certified that the PMSR program was "approved" by the professional accrediting body, the Council on Podiatric Medical Education ("CPME"), and included residents that allegedly lacked permits. But she actually concedes that CPME approval was granted (although she seeks to substitute her own judgment for that of the CPME in arguing that the PMSR program should not have been approved). The Medicare program accepts such approval, along with residents' acceptance and active enrollment in such approved program, as sufficient for the hospital to merit GME funding for that program and those residents. The Medicaid program's requirements for GME funding are even less restrictive.

ARGUMENT

I. THE AMENDED COMPLAINT SHOULD BE DISMISSED BECAUSE IT FAILS TO PLEAD FRAUD WITH THE PARTICULARITY REQUIRED BY RULE 9(b).

A. The Amended Complaint Fails to Identify Bills Submitted by Any Defendant.

Relator argues, against the overwhelming body of decisions in this Circuit dismissing similar complaints,[2] that bills need not be pleaded with particularity, stating that "every element of the who, what, where, why and when of the fraud does not need to be pled with the utmost detail so long as the scheme of fraud itself is specifically and particularly pled." (Opp. at 35

[2] *See, e.g., United States ex. rel. Moore v. GlaxoSmithKline, LLC*, No. 06 Civ. 6047(BMC), 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013); *United States ex rel. Siegel v. Roche Diagnostics, Corp.*, 988 F. Supp. 2d 341, 346 (E.D.N.Y. 2013); *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704(ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009); *United States ex. rel. Mooney v. Americare, Inc.*, No. 06-CV-1806(FB)(VVP), 2013 WL 1346022 at *6 (E.D.N.Y. April 3, 2013); *United States ex. rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 82-84 (D. Conn. 2006); *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 267 (W.D.N.Y. 2010); *United States v. Icahn Sch. of Med. at Mount Sinai*, No. 12 Civ. 5089(GBD), 2015 WL 5472933, at *5 (S.D.N.Y. Sept. 16, 2015); *United States ex rel. NPT Assocs. v. Lab. Corp. of Am. Holdings*, No. 1:07-cv-05696(ALC)(RLE), 2015 WL 7292774, at *6 (S.D.N.Y. Nov. 17, 2015); *United States ex. rel. Corporate Compliance Assocs. v. N.Y. Soc'y for the Relief of the Ruptured and Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292(PKC), 2014 WL 3905742, at *17 (S.D.N.Y. 2014).

(*quoting Pullman v. Alpha Media Publishing*, 2013 WL 1290409 (S.D.N.Y. 2013) at *14).)[3] In *Pullman*, however, the plaintiff alleged specific conversations during which specific misrepresentations were made, and referenced and quoted documentary and videotaped evidence of those misrepresentations. 2013 WL 1290409, at *14. The plaintiff there was considered reliable because she personally observed the misstatements. *Id.* at *2-*4. In contrast, Relator here has not identified a single billing misrepresentation made by anyone, anytime, anywhere.

To sidestep her obligation to identify submitted bills with particularity, Relator argues that conclusory and generalized allegations of submitting false bills are sufficient when there are "particular and reliable indicia" that the allegations are true. (Opp. at 36.) This relaxed pleading standard is not generally recognized in the Second Circuit, however, and the three cases Relator cites from within this Circuit actually undercut her argument.[4]

In any event, Relator offers no such indicia. She references a handful of patients, and offers little about them except that she and other residents entered encounter notes in an electronic medical record system – *not* a billing system – which were reviewed by Dr. Donovan. (Opp. at 38.) She alleges that Dr. Donovan would enter an "attending note," after which time services would be billed to Medicaid and Medicare. (*Id.*) But while an attending physician note could reliably be found in the typical medical record, information regarding bills submitted in

[3] "Opposition" or "Opp." refers to Relator's Memorandum of Law in Opposition to Defendants' Motion to Dismiss dated October 21, 2016. "Moving Brief" or "Mov. Br." refers to the Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint dated July 29, 2016.

[4] *See, e.g., United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.*, 50 F. Supp.3d 497, 509-11 (S.D.N.Y. 2014) (rejecting "reliable indicia" test and holding relators "must allege the false claims themselves with sufficient particularity to satisfy Fed. R. Civ. P. 9(b)."); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 336 (D. Conn. 2004) (requiring plaintiff to plead details about specific bills, but determining complaint sufficiently particularized given information contained about bills, specific patients/procedures, dates of admission, service and discharge, and Medicaid or Medicare reimbursement amounts); *United States v. Huron Consulting Group, Inc.*, 2011 WL 253259, *2 (S.D.N.Y. Jan. 24, 2011) (denying motion to dismiss under relaxed "reliable indicia" standard where complaint referenced substantial billing details for 421 patients, including a chart containing admission dates, lengths of stay, billing codes, account balances, and cost-to-charge ratios). (Opp. at 35-36.)

relation thereto would not (or Relator would certainly have cited it). Indeed, she does not allege that she is familiar with any billing information, or that she participated in billing for services, engaged with staff responsible for billing, or ever even saw or discussed billing or cost reporting.[5] Relator is clear that her responsibilities as resident were limited to "consulting" on outpatient, inpatient, and emergency room patients, and "assisting" on surgical cases. (Opp. at 2; Am. Cplt. ¶ 6.) There is no allegation that her responsibilities extended to tasks related to billing Medicare and Medicaid, or to the preparation and submission of cost reports; nor would such responsibilities be expected for a podiatry resident enrolled in an educational program.

In short, "[a] relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding that as a result of the fraudulent scheme, false claims must have been submitted." *Pfizer*, 2009 WL 1456582, at *5; *see also United States ex rel. Kester v. Novartis Pharmaceuticals Corp.*, 23 F. Supp. 3d 242, 253 (S.D.N.Y. 2014) (same). A relator must "allege the particulars of the false claims themselves." *Corporate Compliance*, 2014 WL 3905742, at *11; *see Yale Univ.*, 415 F. Supp. 2d at 84, 87 (dismissing complaint because "Relator fail[ed] to identify a single false or fraudulent bill submitted to the federal government"); *Johnson*, 686 F. Supp. 2d at 265-67 (dismissing complaint because "[n]owhere in their lengthy pleading do the plaintiffs allege or describe how, *or even if*, any bills for procedures involving falsified records were ever presented to Medicare or Medicaid for payment"). Relator's general and conclusory allegation that Defendants submitted false bills pursuant to "standard operating procedures" – supported neither by bills nor details nor even conversations or meetings observed by Relator that referenced such billing procedures – cannot save her claim.

[5] Although Relator alleges in her Amended Complaint that she was a resident at CIH from 2010 through 2013 (Am. Cplt. ¶ 6), she makes allegations of inadequate supervision of PMSR residents dating back to 2006. (Am. Cplt. ¶¶ 54, 59, 64.) Relator does not allege personal knowledge of misconduct from 2006 through June 2010, nor does she offer any basis for her allegations covering that time period at all.

See Mov. Br. at 20-21; *see also Kester*, 23 F. Supp. 3d at 255; *Yale Univ.*, 415 F. Supp. 2d at 87.[6]

Relator also argues that she should be excused from her failure to plead billing particulars because "the necessary evidence of the essential elements of the claim is within the exclusive control of the defendant" and "the fraud being alleged is part of a complex scheme occurring over a long period of time", involving "numerous occurrences." (Opp. at 37, 39 (*quoting United States ex rel. Ellis v. Sheikh*, 583 F. Supp. 2d 434, 438-39 (W.D.N.Y. 2008)).) But she has not cited a single case in this Circuit where a court has forced a defendant to defend an FCA complaint that provides no detail about the bills themselves. Indeed, two years after Judge Larimer authored *Ellis*, he clarified that even where defendants control the evidence, FCA relators "must still allege a factual nexus between the improper conduct and the resulting submission of a false claim to the government." *Johnson*, 686 F. Supp. 2d at 266; *see also Pfizer*, 2009 WL 1456582, at *5. The court dismissed the FCA claims in *Johnson* because, as here, "the plaintiffs' complaint offers nothing more than conclusory allegations and assumptions that the pattern of incidents that plaintiffs describe ever actually resulted in a fraudulent bill being submitted to Medicare and/or Medicaid for payment." 686 F. Supp. 2d at 266.[7]

II. THE AMENDED COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(b)(6) FOR FAILING TO STATE A PLAUSIBLE FCA CLAIM.

Relator cites extensively the Supreme Court's recent decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which addresses the implied

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[6] Defendants' Moving Brief demonstrated that the Amended Complaint also failed to: (i) distinguish among Defendants' roles in the alleged fraudulent billing conduct, (ii) link each Defendant's actions with a violation of a particular section of the FCA, (iii) allege facts raising at least a strong inference of scienter by each Defendant; and (iv) plead particulars of an alleged agreement that would constitute an FCA conspiracy. (Mov. Br. at 16, 21-23, n.11.) Relator's Opposition fails to address these deficiencies, any one of which alone is cause for dismissal.

[7] As Defendants stated in their Moving Brief, Relator would have referenced, described, and included bills in her Amended Complaint if she knew of any. Thus, her Amended Complaint should be dismissed with prejudice because any amendment would be futile.

certification theory on which she relies. However, she fails to state a claim under this theory, because she fails to plead a material misrepresentation as to services provided or the qualifications of those providing them. (*See* Mov. Br. at 24.)

A. The Amended Complaint Fails to Plead a Material Misrepresentation: The *Escobar* Standard.

Relator misleadingly asserts that here, as in *Escobar*, medical professionals were "unsupervised and unlicensed" and that Medicare and Medicaid require supervision "in order for . . . services to be reimbursable." (Opp. at 20-21.) She claims that *Escobar* illustrates the "strength and validity" of her FCA claims (Opp. at 17), while in fact, it does the opposite.

In *Escobar*, the Supreme Court limited the scope of actionable FCA cases based on omissions to those which "render the defendant's representations misleading with respect to the goods or services provided." 136 S. Ct. at 1999. Accordingly, the Court held that omissions are actionable under the FCA under two conditions: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." 136 S. Ct. at 2001. Neither prong of the *Escobar* test is satisfied here.

The relator in *Escobar* alleged that, "[w]hen submitting reimbursement claims, [the defendant] used payment codes corresponding to different services tha[n] its staff provided," and that "[s]taff members also misrepresented their qualifications and licensing status to the Federal Government to obtain individual National Provider Identification numbers, which are submitted in connection with Medicaid reimbursement claims and correspond to specific job titles." *Id.* at 1997. The Court ruled – as Relator concedes (Opp. at 20) – that it was *these specific representations, included within the claims* submitted to Medicare and Medicaid, that "were

clearly misleading," and that the use of these payment codes "constituted misrepresentations." *Id.* at 2000-01. By contrast, here, Relator alleges nothing about *any* specific representations included on *any* bills submitted to Medicare and Medicaid. She fails to identify with specificity the services alleged to have been billed, offering nothing as to when, where, by whom and to whom they were furnished; she offers no details about the contents of bills, including dates of service, procedure codes, diagnosis codes, codes identifying the providers furnishing the service, or other information required on Medicare and Medicaid billing forms (*see, e.g.,* https://www.emedny.org/info/phase2/PDFS/UB-04%20Sample.pdf). Without identifying such information on the alleged bills, the Amended Complaint fails to identify any false representations.

Having failed to allege a misrepresentation, Relator cannot meet the materiality standard articulated in *Escobar*. 136 S. Ct. at 2004 n.6. The Supreme Court recognized two indicia of a material misrepresentation: (i) "the Government's decision to expressly identify a provision as a condition of payment[, which] is relevant, but not automatically dispositive"; and (ii) "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on compliance with the particular statutory, regulatory, or contractual requirement." *Id. at 2003.* Since *Escobar* was decided, courts have consistently dismissed cases like this one, where a relator fails to allege either the contents of bills that contain a misrepresentation or specific facts supporting materiality.

In *United States ex rel. Scharff v. Camelot Counseling*, 13-cv-3791 (PKC), 2016 WL 5416494 (S.D.N.Y. Sept. 28, 2016), the allegation was that a substance abuse and rehabilitation center "failed to keep adequate notes about patients, billed time incorrectly and maintained records that contained apparent discrepancies between patient signatures." *Id.* at *1. The court

rejected the FCA claim on materiality grounds, quoting *Escobar*: "[t]he materiality standard is demanding because the FCA is not a vehicle for punishing garden-variety breach of contract or regulatory violations." *Id.* at *8. The court noted the conclusory nature of the complaint's assertions that the defendant "failed to comply with material Medicaid regulations that served as conditions precedent for Camelot to receive reimbursement through federal funds for the services that Camelot provided"; the court then determined, in an analysis that applies equally here, that such a pleading fails because it "does not connect specific conduct by Camelot's counselors to specific submissions for reimbursement, or explain why the purportedly fraudulent conduct was material to the payment of reimbursements. The Complaint does not cite any express condition for reimbursement applicable to Camelot, nor does it allege whether the government has refused to reimburse clinics that have engaged in conduct similar to Camelot's." *Id.*

In *United States v. Northern Adult Daily Health Care Center*, 13-CV-4933 (MKB), 2016 WL 4703653 (E.D.N.Y. Sept. 7, 2016), Judge Brodie granted a motion to dismiss FCA claims brought under a theory of implied certification, "[b]ecause Relators have not alleged that noncompliance with . . . regulations listed in the Amended Complaint would have influenced the government's decision to reimburse" the defendant. *Id.* at *12. There, unlike in this case, the relator actually did include sample bills to demonstrate specific misrepresentations that had been made, but neglected to allege facts to demonstrate that the misrepresentations were material. For that reason, the court rejected the implied certification theory.[8]

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[8] *See also United States ex rel. Dresser v. Qualium Corp.*, Case No. 5:12-cv-01745-BLF, 2016 WL 3880763, at *6 (N.D. Cal. July 18, 2016) (granting motion to dismiss complaint that states "the government would not have paid Defendants' claims had they known of Defendants' fraudulent conduct" but "does not explain why" the government would not have paid the claims); *United States v. Fulton County, Ga.*, 1:14-cv-4071-WSD, 2016 WL 4158392, at *8 (N.D. Ga. Aug. 5, 2016) (dismissing FCA claims with prejudice because "Relators have not shown that Defendants misrepresented matters so central to the Contract that the government would not have paid [Defendants'] claims had it known of these violations.").

B. The Amended Complaint Does Not Allege Any Misrepresentation About Compliance With Any Statutes or Regulations Material to Payment.

1. Billing for Professional Services.

Relator mistakenly argues that the "Teaching Physician Rule", 42 C.F.R. § 415.172, makes "physician supervision of . . . resident[s]" a condition of payment. (Opp. at 23). But the Teaching Physician Rule actually requires only that a podiatrist be physically present during "critical or key portions of the service" *if* the podiatrist is billing Medicare for professional services in cases where a resident furnished care. (Opp. at 23-24.) This is to ensure that Medicare pays for physicians' professional services only where physicians have personal involvement in the care provided, beyond what is required merely to supervise a resident who provides the hands-on service. (*See* Mov. Br. at 7-8.) The services of residents, who may operate independently from physicians, instead are payable through the separate mechanism of GME payments to the hospital.[9]

Defendants concede that Dr. Donovan theoretically could be in violation of the Teaching Physician Rule if it were adequately alleged that he was absent for professional services billed under his name to Medicare. However, the Amended Complaint does not specify even one Medicare claim for professional services. (*See* Mov. Br. at 29.) For Medicaid, as Relator concedes (Opp. at 24-25), podiatrists' professional services are not reimbursed separately, but are bundled into the payment for hospital services; the Teaching Physician Rule is inapplicable.

2. Billing for "Unsupervised" Hospital Services.

Relator concedes that the Teaching Physician Rule does not apply to billing for hospital

[9] "[S]ervices performed by the resident *alone* are . . . paid for . . . through the GME and IME payments [to the hospital]." Dep't of Health and Human Servs., Office of the Inspector General, Semiannual Report, October 1, 2000 – March 31, 2001, p. 10 (https://oig.hhs.gov/publications/docs/semiannual/2001/01ssemi.pdf (last visited Nov. 19, 2016)). *See also* 60 Fed. Reg. 63124, 63144 (Dec. 8, 1995) (CMS acknowledging residents may operate "largely unsupervised").

services. (Opp. at 25.) Instead, she argues that billing would have been improper because the residents were "unsupervised." (Opp. at 22-23.) She uses the term "unsupervised" colloquially and subjectively, but she does not plausibly allege an absence of the particular level of supervision actually required *by the Medicaid and Medicare programs*.[10]

For example, Relator disregards CMS's express decision to forego any "explicit supervision requirements in [Medicare] regulations" regarding inpatient hospital services, the agency having determined that sufficient qualified practitioners would be available whenever inpatient hospital services were furnished. (*See* Mov. Br. at 27 (*quoting* 74 Fed. Reg. 60316, 60582).) By contrast, outpatient hospital services require, as a general rule, only the "direct supervision" (*i.e.*, "immediate availability") of a physician or non-physician practitioner, with CMS designating, by procedure code, those services for which either the greater level of "personal supervision" (*i.e.*, a supervisor "in attendance in the room during the performance of the procedure"), or the lesser level of "general supervision" (*i.e.*, under a supervisor's overall direction and control) is required; in fact, CMS has declined to designate any service as requiring personal supervision, but has designated some as requiring only general supervision.[11]

By failing to identify *any* claims for hospital services that would indicate the location in which they were furnished, or *any* procedure codes on alleged claims that would indicate the required level of supervision, or *any* dates of service and patient identifiers that would allow

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[10] Relator's assertions that there was a "total absence of supervision" is at odds with her descriptions of the residents' duties as "*consulting* on" inpatient, clinic and emergency room patients, and "*assisting* on surgical cases" (*see, e.g.*, Opp. at 2, 6, 7; Am. Cplt. ¶ 6, 70, 75); she also concedes that Dr. Donovan "*did make himself available to supervise* surgical procedures performed by residents in the CIH operating rooms" (Opp. at 3; Am. Cplt. ¶ 79).

[11] 42 C.F.R. §§ 410.27(a)(1)(iv)(A), (B); *see* 42 C.F.R. §§ 410.32(b)(3) (i), (iii); CMS, Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level (Mar. 10, 2015) (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Hospital-Outpatient-Therapeutic-Services.pdf) (last visited Dec. 1, 2016).

verification of the supervising hospital staff required and available when services were provided, Relator has failed even to meet the first prong of the *Escobar* standard – that there be a representation on a claim that is alleged to be false by virtue of non-compliance with standards applicable to the services presented. Relator argues that Dr. Donovan should be "*personally* involved" in any services for which Defendants have billed (Opp. at 12, 14),[12] but she cannot substitute her opinion as to adequate supervision for that of the federal agency, which has decided otherwise. Nor can an alleged lack of supervision render a representation false with respect to Medicare billing, for example, for services furnished by Relator herself on or after February 1, 2012, when she became licensed, and therefore, capable of furnishing billable hospital services without supervision. *See* 42 C.F.R. § 410.27(a)(1)(iv)(A); Am. Cplt. ¶ 29, *citing* 42 U.S.C. § 1395x(r); Reply Declaration of Joseph V. Willey, dated Dec. 2, 2016 Ex. 1 (showing Relator's licensure commencing February 2012).

As for Medicaid, the provisions cited by Relator (Opp. at 26) merely clarify that "personal and identifiable services" furnished to inpatients in a teaching hospital must be provided either by the attending physician, or by residents with "oversight by the attending physician," and say nothing about the requisite level of such "oversight." Neither "oversight" nor "appropriate supervision" (*see*, Opp. at 27, *citing* New York State Medicaid Update, June 2009, Volume 25, Number 7) mandates the constant physical presence of the attending that Relator alleges is required, and she fails to identify any Medicaid payment standard that was allegedly violated.[13] Moreover, her assertion that residents were "wholly unsupervised" is at odds with her

[12] *See, e.g.*, allegation that Dr. Donovan seldom *attends* emergency room visits, or has a *personal role* in the care of patients. (Am. Cplt. ¶ 61; *see also* Opp. at 12-13).

[13] Relator cites 10 N.Y.C.R.R. § 405.4(f) as requiring "continuous monitoring" of residents' patient care services, and "preoperative and postoperative 'examination and assessment' of all surgical patients by 'attending physicians.'" (Opp. at 27) Yet, she fails to note that violations of these hospital code provisions

acknowledgements that she was often in contact with Dr. Donovan by text and phone regarding the treatment of patients (Opp. at 3,4).

3. Billing for Hospital Services In Which Residents Allegedly Lacking Limited Residency Permits Participated As Part of Their Training.

There is no Medicare or Medicaid provision that conditions payment for hospital services on a resident having a limited residency permit,[14] which a resident in a hospital GME program is required to obtain. *See* New York. Educ. Law § 7008. Relator thus seeks to shift focus to State laws that require *licenses* to practice medicine or podiatry. *See* Opp. at 28-29, 32. In contrast to an LRP, a license allows a graduate of a program of professional education in podiatry to practice the "profession of podiatry." New York Educ. Law §§ 7001, 7002, 7004.

Accordingly, Relator's attempted analogy of this case to *Escobar* falls flat. The allegations in *Escobar* were that employees of the defendant mental health facility had no *licenses* under a Medicaid regulatory regime unambiguously requiring the treating professionals to be licensed (136 S. Ct. at 2000-01), and that those employees were identified on bills as having provided specific services for which they were unlicensed. Here, Relator's allegations concern the provision of services by residents-in-training, who are *not* required or expected to be licensed under the applicable regulatory regime. No specific information about any bill is alleged, nor is it alleged that residents without LRPs were ever identified, or identified in a misleading manner, on any bill. Moreover, the Amended Complaint fails to include any particularized allegations of any service in which unpermitted residents participated without

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are addressed primarily through "Statements of Deficiencies", corrective action plans, and fines when warranted (she also does not identify any pre- or post-operative examinations that were performed by residents in the attending physicians' absence). *See* N.Y. Pub. Health Law §§ 12, 2803(1)(a); DOH, About Hospital Inspections, http://profiles.health.ny.gov/hospital/pages/about_inspections.

[14] Relator does not dispute Defendants' argument (*see* Mov. Br. at 32-33) that participation of a resident lacking an LRP would have no bearing on Medicare or Medicaid's decision to accept or reject a bill for Dr. Donovan's professional services. Here, we address hospital services.

another provider present who was authorized to supervise; it alleges that the two unpermitted residents "assisted" in several surgeries on specific dates, which implies that they were, in fact, supervised. (Am. Cplt. ¶¶ 70, 75.) And finally, Relator fails to cite a single statute or regulation to support her argument that a resident's failure to obtain or renew an LRP (as opposed to a practitioner's license being suspended or revoked) (Opp. at 29), would be material to Medicare's or Medicaid's payment decisions.

4. Claiming GME Reimbursement.

Relator claims that cost reports claiming GME funding were misleading because "they did not disclose the fraud permeating the PMSR program at CIH . . ." (Opp. at 22.) As Relator concedes, however, GME funding is determined and conditioned only on "the number of Full-Time Resident Equivalents" and whether the PMSR program was approved by the CPME.[15] (Opp. at 30, 32.) The Amended Complaint does not identify any representations made in those cost reports that are false (Am. Cplt. ¶ 97); in fact, Relator cannot (and does not attempt to) plausibly allege that the PMSR program was *not* approved or that Defendants misrepresented the number of residents enrolled and actively participating in the PMSR program. Accordingly, there is no actionable misrepresentation under the standards set forth in *Escobar*. 136 S. Ct. at 2001.[16]

Relator lists seven bulleted items in her Opposition "concerning the fraudulent nature of

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[15] Relator cites regulations which she claims require GME costs to be "reasonable" and "necessary for the efficient delivery of the service." (Opp. at 31 (citing, e.g., 42 C.F.R. §§ 413.13(a); 413.30(a)(2)).) The cited regulations, however, do not concern GME costs at all. In fact, the first of these sections, which specifies Medicare's reimbursement methodology for patient care services, expressly excludes GME costs – including all resident compensation – from the reimbursement calculation, because they are funded separately. 42 C.F.R. § 413.13(a), (d).

[16] Relator also cites inapposite case law to support her position. In *United States ex rel. Feldman v. Van Gorp*, 697 F.3d 78 (2d Cir. 2012), the Second Circuit held that certain misrepresentations would influence an agency's decision to approve or reject a grant renewal. *Id.* at 96-97. The parties there stipulated that NIH regulations required the defendant to make specific representations about key personnel that were not made and thus, the misrepresentation itself was not at issue. 697 F.3d at 93. In contrast, here, there is no misrepresentation, much less a misrepresentation that could impact CMS's payment decision.

the PMSR program" (*e.g.*, "The program had numerous training and policy deficiencies") (Opp. at 32-33). But she does not specify any statements within any cost reports that are rendered false by this alleged conduct, nor allege that it violated any statutes or regulations, or that it was material to any government payment decisions. Indeed, the PMSR program was, at all relevant times, approved by the CPME, even after Relator brought the alleged misconduct to its attention. (Opp. at 32; Mov. Br. at 37-38.) Relator also does not dispute that Medicaid GME payments are not contingent on such approval. (*See* Mov. Br. at 37.)

III. CLAIMS AGAINST NYC HEALTH + HOSPITALS UNDER THE NYFCA SHOULD BE DISMISSED FOR LACK OF JURISDICTION.

Relator concedes that she is barred from suing NYC Health + Hospitals under the NYFCA, and those claims should accordingly be dismissed against it. (Opp. at 16 n.1.)

CONCLUSION

For the reasons set forth herein and in Defendants' Moving Brief, Defendants respectfully urge the Court to dismiss the Amended Complaint in its entirety with prejudice.

Dated: New York, New York
December 2, 2016

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